DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

# Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
**(Reference Member State)**

## PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

**Thiamavance 10 mg/ml oral solution for cats**

CORREO ELECTRÓNICO

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## PRODUCT SUMMARY

| | |
|---|---|
| EU procedure number | ES/V/0449/001/DC |
| Name, strength and pharmaceutical form | Thiamavance 10 mg/ml oral solution for cats |
| Applicant | VIRBAC<br>1ere Avenue 2065 m-L.I.D.<br>Carros Cedex<br>F-06516 - France |
| Active substance(s) | Thiamazole |
| ATC vetcode | QH03BB02. |
| Target species | Cats |
| Indication for use | For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.<br>For the long-term treatment of feline hyperthyroidism. |

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|---|---|
| Thiamavance 10 mg/ml oral solution for cats | ES/V/0449/001/DC |
| Virbac | DCP |
| Publicly available assessment report | |

## PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

## SUMMARY OF ASSESSMENT

| | |
|---|---|
| Legal basis of original application* | Hybrid application in accordance with Article 19 of Regulation (EU) 2019/6 as amended. |
| Reference product (RP) | Felimazole 5 mg comprimidos recubiertos para gatos |
| Marketing authorisation holder | DECHRA VETERINARY PRODUCTS S.L. |
| Marketing authorisation number | 1594 ESP |
| EU procedure number | IE/V/0505/003/MR |
| Date of authorisation | 19/10/2004 |
| Date of completion of the original decentralised procedure | 26/11/2025 |
| Concerned Member States for original procedure | AT, BE, CY, CZ, DK, DE, EE, EL, FI, FR, HU, IT, LT, LV, LU, MT, NL, NO, PL, PT, RO, SE, SK, UK(NI) |
| Withdrawn CMS during original decentralised | - |

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

## 1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

## 2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

### 2.A. Product description

The VMP contains 10 mg/ml of thiamazole as active substance and glycerol, liquid sorbitol (non-crystallising) and vanillin as excipients.

The container/closure system is an amber type III glass bottle of 30 ml nominal capacity with a clear white polypropylene or polyethylene (LDPE) syringe adaptor, and a childproof white polypropylene cap. The secondary packaging consists of standard cardboard box.

The product is supplied with a clear 1 ml polypropylene syringe with 1.25 mg graduation increments or a clear 1 ml polypropylene syringe with 0.5 mg graduation increments, beginning from 0.5 mg.

The choice of the absence of preservative is justified.

The VMP is an established pharmaceutical form, and its development is adequately described in accordance with the relevant European guidelines.

### 2.B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

### 2.C. Production and control of starting materials

The active substance is thiamazole, an established active substance described in the European Pharmacopeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

### 2.D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

### 2.E. Control tests on the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

## 2.F. Stability tests

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

## 2.G. Other information

Not applicable.

## 3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users and the environment.

### 3.A. Safety tests

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated the safety profile of the reference product can be assumed.

***User safety***

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that the main user of this veterinary medicinal product is a pet owner and is considered a non-professional user. Therefore, the product is kept in the household and young children may get access to the product when not properly stored.

The worst-case scenario for user safety would be accidental oral ingestion by children. Other potential concerns include accidental oral ingestion (hand to mouth) by an adult, especially for pregnant or nursing women due to the teratogenic potential of the active substance.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

***Environmental Risk Assessment***

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

***Phase I:***

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will only be used in non-food animals.

## 4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, data to support efficacy and safety in the target species are not required. The applicant has provided a study to demonstrate bioequivalence between the VMP and the reference VMP. In order to omit carrying out efficacy and safety studies in the target species, bioequivalence between the VMP and the reference veterinary medicinal product has been demonstrated.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

## 5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

## POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.

None.